K 060483

JUN 23 2006



## 510(k) SUMMARY

*The 510(k) Summary is submitted as required by Section 807.92(a)*

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|---|---|
| **Submitter Name:** | Volcano Corp. |
| **Contact Person:** | Michelle J. Badal, RAC<br>Manager, Regulatory Affairs |
| **Address:** | 2870 Kilgore Road<br>Rancho Cordova, CA 95670 |
| **Phone Number:** | 916-231-4497 |
| **Fax Number:** | 916-638-2647 |
| **Date Prepared:** | February 23, 2006 |
| **Device Trade Name:** | **AIM – Angio-IVUS Mapping System** |
| **Device Common Name:** | Intravascular Ultrasound Imaging System |
| **Classification Name, Number, Product Code:** | Echocardiograph<br>21 CFR 870.2330, Product Code: DXK |

**Predicate Device:**
The Volcano Angio-IVUS Mapping System is substantially equivalent to the Volcano InVision System cleared under K031148 on May 28, 2003, and the Paieon CardiOp-B System cleared under K030139 on April 2, 2004.

**Device Description:**
The Angio-IVUS Mapping System is an image acquisition and processing system on the In-Vision Gold Imaging console designed to process traditional X-ray angiographic images. A standard Ethernet cable links the In-Vision Gold Imaging System to the catheterization lab DICOM network, allowing the angiographic images to be transferred to the Angio-IVUS Mapping System. The system can be used to make a 3D reconstruction of a coronary sub-tree from two angiogram images taken at different angles. IVUS pullbacks acquired with the In-Vision Gold System can be mapped to the 3D reconstruction and the original 2D angiograms, resulting in a better tool for IVUS orientation and interpretation. In addition, Volcano's VH IVUS can (optionally) be performed, combining the detailed information of the arterial wall with the familiar angiographic roadmap.

**Intended Use:**

The Volcano Angio-IVUS Mapping System is intended to provide a common frame of reference for intravascular ultrasound and angiographic images during diagnostic and/or interventional procedures for the coronary vasculature. The system provides indication of the location of the IVUS cross-sectional imaging plane for any given IVUS image as it relates to a two-dimensional (2D) angiographic image and/or the associated three-dimensional (3D) model formulated from multiple 2D image projections.

**Performance Data:**

The information provided in the premarket notification demonstrates that the Angio-IVUS Mapping System is substantially equivalent to the predicate devices, for which there is FDA clearance. This equivalence was demonstrated through comparison of intended use and fundamental scientific technology to a commercially available device. The information supplied in this premarket notification provides reasonable assurance that the Angio-IVUS Mapping System is safe and effective for the stated intended use.

**Conclusion:**

The Volcano Angio-IVUS Mapping System has the same indication for use, and utilizes the same *fundamental scientific technology* as that of the predicate devices. The information provided in this premarket notification submission, along with the Declaration of Conformity to design controls supports a determination of substantial equivalence of the Volcano Angio-IVUS Mapping System to the predicate devices.

K06 0483

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

Volcano Corporation
Ms. Michelle Badal
Manager, Regulatory Affairs
2870 Kilgore Road
Rancho Cordova CA 95670

Re: K060483
Trade/Device Name: Angio-IVUS Mapping System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, IZI
Dated: May 19, 2006
Received: May 22, 2006

Dear Ms. Badal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K060483

Device Name:

Volcano Angio-IVUS Mapping System

Indications for Use:

The Volcano Angio-IVUS Mapping System is intended to provide a common frame of reference for intravascular ultrasound and angiographic images during diagnostic and/or interventional procedures for the coronary vasculature. The system provides indication of the location of the IVUS cross-sectional imaging plane for any given IVUS image as it relates to a two-dimensional (2D) angiographic image and/or the associated three-dimensional (3D) model formulated from multiple 2D image projections.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060483

*(Posted November 13, 2003)*